Aalto Scientific, Ltd.

K062668

510(k) Summary

A. Submitter

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OCT 16 2006

B. Contact Person

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C. Date of Summary Preparation

September 2006

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ Immunoassay Linearity Set
Common Name:	Immunoassay Linearity
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

E. Device to Which Substantial Equivalence is Claimed

Audit™ MicroCV™ General Chemistry Linearity Set
Aalto Scientific, Ltd., Carlsbad, CA
K042318

Aalto Scientific, Ltd.

F. Description of the Device

The Audit™ MicroCV™ Immunoassay Linearity Set is a Human and Bovine serum albumin based, lyophilized, five level set of QC material, with each level containing 17 analytes. It is used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification for the analytes listed using FDA accepted reagents for the appropriate instrumentation in accordance with current CLIA-88 guidelines and regulations. In addition, Level A – E of this product may be used as an unassayed quality control material for these analytes or as an assayed quality control material for the analyzer systems specified in the package insert. Where Level A is near the lower limit of instruments and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E. It is not intended to be used as an assayed quality control material for any other analyzer systems.

G. Statement of Intended Use

The Immunoassay Linearity Set is intended to simulate human patient serum samples for the purpose of verifying and validating the Analytical Measurement Range for non-waived immunoassay testing methods as identified in the package insert.

H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit™ MicroCV™ Immunoassay Linearity Set (New Device)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Intended Use	Linear, calibration verification quality control material	Linear, calibration verification quality control material
Number of Analytes per vial	17	30
Number of levels per set	5	5
Contents	5 x 5 mls	5 x 5 mls
Matrix	Human and Bovine Serum Albumin	Human Based Serum
Type of Analytes	Immunoassay	General Chemistry
Form	Lyophilized	Lyophilized
Preservative	Yes	Yes
Storage	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Reconstituted Stability	5 days at 2 to 8° C	7 days at 2 to 8° C except for enzymes and bilirubin, which are 48 hours

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I. Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Audit™ MicroCV™ Immunoassay Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Reconstituted Stability: Once a vial has been reconstituted, all analytes will be stable for 5 days when stored tightly capped at 2 - 8° C.

Shelf Life: Two years, when stored unopened at 2 - 8° C.
Note: Real time studies are ongoing to support the shelf life of this product.

J. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Alan Vekich
Regulatory Affairs Specialist
Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008

OCT 16 2006

Re: k062668
Trade/Device Name: Audit™ MicroCV™ Immunoassay Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: September 8, 2006
Received: September 13, 2006

Dear Mr. Vekich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062668

Device Name: Audit™ MicroCV™ Immunoassay Linearity Set

Indications For Use:

The Audit™ MicroCV™ Immunoassay Linearity Set consists of five levels in Human and Bovine serum albumin matrix. Each level contains the following analytes: Cortisol, Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, Total T3, Total T4, TSH, and Vitamin B12. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments.

This product may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations.

In addition, Level A – E of this product may be used as unassayed quality control material for these analytes or as an assayed quality control material for the analyzer systems specified in the package insert. It is not intended to be used as an assayed quality control material for any other analyzer systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)